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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,266	01/17/2002	Ernst Heinz	VOS-29	1286

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/053,266	Applicant(s) HEINZ ET AL.	
	Examiner Georgia Helmer	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Office Action

Status of the Claims

1. The Office acknowledges receipt of Applicant's Response; dated 8 November 2006.
2. Claims 1 and 4-23 are pending, and are examined in the instant action.
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. This action is made FINAL.

Claim Rejections - 35 USC § 112 Enablement

6. Claims 1 and 4-23 remain rejected under 35 U.S.C. 112, first paragraph, for reasons of record set forth in the Office Action mailed 24 April 2006 as well as those set forth below.

Applicant's arguments filed 8 November 2006 have been fully considered, but are not deemed persuasive.

Evidence of unpredictability at each step of the claimed method has been demonstrated by the Examiner. Applicant's assertions are insufficient to rebut the evidence provided by the Examiner to demonstrate the unpredictability of the claimed invention.

Applicant traverses the Examiner's argument that Applicant's cited evidence is "used in the specification to demonstrate the difficulties of the state of the art at the time

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of filing". Applicant further states that "the Examiner refers to the specification on p. 2, lines 17-23:

Hence, the production of flax primary transformants, if at all possible, seemed to be genotype-dependent, time-consuming and/or resulting initially in plants with aberrant morphology" (specification p.2), emphasis added. The specification continues: "Thus the technical problem underlying the present invention is to provide a reliable and efficient method for the generation and selection of stable transformed plant of the genus *Linum*."

See Response of 8 November 2006, p. 6 bridging p.7.

Applicant argues that the Examiner "is mistaken. She is equating the step of introducing a recombinant DNA molecular into a flax cell, as recited in step (a) of claim 1, with the "technical problem" of generating and selecting stable flax transformants as recited in the passage above". Applicant argues further "[t]he technical problem is not the introduction of DNA into a flax cell, which is easy and straightforward. Rather, the technical problem relates to the *selection* of stably transformed plants of the genus *Linum*". See Response of 8 November 2006, p.7, 1st ¶ lines 1-5.

Applicant's arguments are not commensurate in scope with the claims.

None of the claims presently being examined recite the "selection of stably transformed plants". Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the claims encompass the step of introducing foreign DNA into flax, as recited in part (a) of claim 1, and recovering whole transgenic flax plants, as recited in part (e) of claim 1; both of which have been demonstrated to have been unpredictable, as stated in the last Office Action. The prior art cited by the Examiner demonstrates the difficulty in obtaining high frequencies of,

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and/or morphologically normal, flax transformants. The cited prior art also discusses genotype dependence and explant type as contributing factors to said unpredictability, in addition to antibiotic type.

Applicants traverse primarily the Examiner's rejection of claims 1 and 4-23 as not containing all the essential elements of the invention. Applicants contend that *Agrobacterium* is not an essential element of the claimed invention, but that *Agrobacterium* is just one of many approaches for successfully and simply introducing DNA into flax cells. (Response of 8 November 2006, p.7, final ¶).

Applicant's traversal is unpersuasive. Applicant's assertions are insufficient to rebut the evidence provided by the Examiner to demonstrate the unpredictability of the claimed invention.

Applicant traverses ^{the} Examiner's maintaining "that another essential element—one of the specific antibiotics recited in claim 4—is missing from the claims." (Response of 8 November 2006, p.8, 1st ¶). Applicant argues that "[a]gain the Examiner is mistaken. The specification discloses that other antibiotics (eg. hygromycin, see line 30 on page 13) may be used in the disclosed invention. Thus the claimed invention is not limited only to those antibiotics recited in claim 4 and on page 7 of the Office Action."

Applicant's traversal is unpersuasive. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, Applicant's specification merely asserts that hygromycin may work, without supplying

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any data to prove this assertion. Such a mere assertion, when weighed against the evidence provided by the Examiner, is not probative.

Applicant traverses primarily that US 5,973,227, issued 26 October 1999, describing transformation of flax hypocotyls by particle bombardment, is available as post-filing date support for the teachings of the instant specification. (Response of 8 November 2006, footnote, p. 6.)

Applicant's traversal is unpersuasive. US 5,973,227 issued 26 October 1999, was not available as of the filing date of the instant case, 20 July 1999. See *In re Glass*, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

Even if the US 5,973,227 disclosure were available as of the date of filing of the instant case, it is the instant specification that should be enabling, not the prior art. Furthermore, the mere germ of an idea does not constitute an enabling disclosure, and the specification, not the knowledge of one skilled in the art must supply the enabling aspects of the invention. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2nd 1001, 1005 (Fed. Cir. 1997).

Furthermore, the US 5,973,227 patent presents numerous modifications and requirements for successful microprojectile transformation of flax. These modifications and requirements are absent from the instant specification. For example, use of "flax hypocotyl tissue comprising epidermal tissue" (claim 1) and preculturing the hypocotyl

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tissue for a period of 4 days on a medium consisting of 3% sucrose, 0.8% agar, 1.0 mg/l/L BA and 0.02 mg/L NAA (column 4, lines 45-53).

Claims 22 and 23, drawn to a transgenic *Linum usitatissimum* cells, callus tissue or plant of claim 1, or a harvest part of said *Linum usitatissimum*, remain rejected because the method of claim 1 is not enabled.

Remarks

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 10-6 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer
Patent Examiner
Art Unit 1638
January 19, 2007

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

